OVERVIEW

Risk Assessment in California and the Need for Further Investigation to Insure Infant and Child Protection

DR. MARTY: Thanks, Mark.

I'm Melanie Marty and I'm Chief of the Air Toxicology and Epidemiology Section at OEHHA, and one of the reasons we're here today is because of the passage of some legislation in California that is going to have, I think, broad-reaching impacts in terms of how we assess risk of chemicals in our environment.

Senate Bill 25 was written by Martha Escutia and it was passed after much hair-tearing and two legislative sessions, and it essentially has provided us with a mandate -- and also money, that's always nice -- to ascertain whether our risk assessment methods protect infants and children.

I'm sure a lot of the audience is familiar with risk assessment so you know what we currently do for a noncancer risk assessment; we generally use a tenfold uncertainty factor to account for intraspecies variability, or intra-individual variability in the human population, and we assume that we're including kids when we do that. But it really is an assumption, because we really don't know all that well if that is adequate, at least for some chemicals.

In cancer risk assessment, we typically use data either from occupational epidemiology studies where we're looking usually at white males, or at least always at adults, we're never looking at kids in occupational settings. If we don't have human data, we use cancer bioassays in animals, and the vast majority of them are started when the animals are sexually mature. So we're really not looking at what happens when you give a carcinogen to a young animal.

There has been a lot more emphasis on this issue recently, so there are a lot of good studies that are currently being conducted, some of them funded at least partially by U.S. EPA, that are looking at perinatal and prenatal exposures. I think that these studies will give us a lot of information and help point us in the right direction.

At OEHHA we are committed to evaluating all of the available information to help us understand differences between children and adults, including infants, that might influence the response to toxicants.

We've been hearing from the pediatric community, and people like Lynn and other folks, for some time that kids are not just miniature adults. We're taking a look more at things like pharmacokinetic models. Typically with pharmacokinetic models, you're using the 70 kilogram human that breathes 20 cubic meters per day and has the cardiac output and organ perfusions of an adult male, and so on. We can now build models and use inputs to those models that are specifically for infants and children.

We're also looking more in-depth at toxicology experimental evidence where the studies exposed animals either in utero or perinatally to look for differences between how those animals reacted and how adult animals reacted.

We already know, for example, that with exposure to vinyl chloride, you're going to get a higher tumor yield if you expose those animals when they're young. We have evidence for a number of carcinogens now that you can get higher tumor yields when the animals are exposed in utero or perinatally and prior to maturity.

We're also evaluating the pharmaceutical literature, because here you have chemicals that are given to adults and they're given to kids, and there's well-known differences in how kids react versus adults. Ritalin is a good example. There's all kinds of good examples from the pharmaceutical literature where we can try to look at the underlying bases for the differences and then project that out to exposures to environmental chemicals.

So, under Senate Bill 25 we'll be prioritizing our criteria air pollutants, those are the ones that have an ambient air quality standard associated with them.

We're prioritizing them for re-review based on whether we think that ambient air quality standard actually is adequate for protecting infants and children.

And we are pulling in a lot of outside expertise to help us do this, mostly from researchers who've actually studied the impact of criteria air pollutants on kids in epidemiology studies or chamber studies.

In California Toxic Air Contaminants (TAC) are identified by the Air Resources Board. There's a legal definition for toxic air contaminant, it includes the federal hazardous air pollutants. We're going to be developing a list of TACs, toxic air contaminants, that differentially impact children, and this is going to be an open public process with public review and peer review by the state's Scientific Review Panel on toxic air contaminants.

We're also embarking on a reevaluation of our risk assessment methods, and if we need to change them we're going to change them. That is a slightly longer-term scenario than just developing a list. And, I'd like to also add that the Air Resources Board has a lot of duties under that legislation.

The statute also specifically requires us to look at not just the sensitivity differences, including how pharmacokinetics or pharmacodynamics might impact the differences in response to toxicants, but also exposure differences. For example, infants are low to the ground, so if you're talking about mercury vapor they're going to get a higher dose because it's hanging out down at the carpet. Kids drink, eat and breathe more per unit body weight than adults, we need to take that into account specifically.

We also need to look at effects of mixtures that act in the same way, so right now we use the hazard index approach for noncancer effects, which has been the standard approach for a long time, and we need to see whether that approach really is

adequate. In addition, we will be looking at the impacts of age-at-exposure to carcinogens.

And finally, we're going to be looking at interactions of criteria air pollutants which have typically been stuck in a box and treated differently, and toxic air contaminants.

Okay, that's all I had to say for opening remarks.

George is going to come up here. George Alexeef is our Deputy Director for Scientific Affairs at OEHHA, and he's got a few words, and he's going to introduce our keynote speaker.

KEYNOTE ADDRESS

DR. ALEXEEF: Good morning, everyone. As people continue to pile into the room here, first of all I want to welcome you all here, and I know that we've all been looking forward to this symposium with great anticipation. I want to thank Mark Miller and Melanie for putting together a great list of speakers and organizing this conference, and I'm sure there're a lot of other people involved as well. I don't know all their names, but I'd like to thank them all.

And I think that this is a meeting that, if you've talked with our staff, or if you're a member of our staff, you know that we're going to be having a lot of symposia on some interesting issues such as children's health; this is the beginning of a number of these types of workshops.

I'd like to just start -- as most of you probably know, a member of our staff recently died, Hanafi Russell. He was a research writer and he developed a lot of our public-oriented documents including our toxics directory. He was also a father of several children, plus about five foster children. So I thought we'd just have a brief moment of silence for Hanafi since he passed away this week.

(Moment of silence.)

Okay. Well, I think our keynote speaker today is someone who we're very happy to have Dr. Lynn Goldman, who I'm sure many if not most of you know. She's a pediatrician and epidemiologist. She got her degree in epidemiology, a Master's in Public Health, from Johns Hopkins, and her M.D. at the University of California in San Francisco, and she's specialized in pediatrics.

Currently she's an adjunct professor at Johns Hopkins, at the School of Hygiene and Public Health, and is a principal investigator on children's health for the Pew Environmental Health Commission.

Prior to that she was at the Environmental Protection Agency as Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substance Control.

And although it's not mentioned in her bio, previous to that, as many of you know, she was with the Department of Health Services here in California. And in fact Lynn and I go back at least 15 years. When I started here as a staff member Lynn was a Unit Chief, and then a Section Chief, and then a Branch Chief, and she developed one of the cornerstones of our division at that time, the Division of Environmental Health Hazard Assessment which, as you might guess, became the Office of Environmental Health Hazard Assessment.

And so we thank Lynn for all the work she did in terms of building our department from about 10, 12, 15 people to both a large department of over a hundred, as well as a large group still in Department of Health Services.

So I want to welcome Lynn back, and look forward to hearing what you say. (Applause.)